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SUBJECT: PAKISTANI PHARMACEUTICAL INDUSTRY IN CRISIS

¶1. (SBU) Summary: On August 26, Econoffs met with Dr. Shujaiddin Shaikh of Merck Sharpe and Dohme (MSD) and Dr. Iqbal Bengali of Pfizer regarding issues facing Pakistan's pharmaceutical industry. The GOP has not allowed an adjustment of pharmaceutical prices for over seven years. Domestic and multinational companies as well as trade associations feel that the industry will no longer be viable if the pricing issue is not resolved, which could lead to a shortage of medications on the Pakistani market. Undisclosed data protection - currently at a standstill within the Ministry of Health (MOH) - is still an issue for multinational firms, but it now takes a back seat to pricing. Shaikh and Bengali were both positive about a Bilateral Investment Treaty (BIT) and thought that industries (not just pharmaceuticals) might be willing to approach the GOP to advocate for a BIT. End summary.

#### Pricing Issues

¶2. (SBU) Bengali and Shaikh discussed the increasingly dire pricing situation for pharmaceuticals in Pakistan. They said that the industry had not been allowed to raise prices in seven years, not even to adjust for inflation. Noting cost increases in oil, raw materials and commodities, along with a weak rupee, they stressed the entire Pakistani pharmaceutical industry (both domestic and multinational) will soon no longer be sustainable. MSD sold its Pakistan operations to a local company, Organon Bio Sciences (OBS), in April. Bengali said he had already seen a letter from Bristol Myers Squibb (BMS) to Pfizer noting that BMS has plans to leave the Pakistani market. Bengali and Shaikh both felt that if the pricing issue was not addressed soon, more companies might abandon the market. Shaikh said that all of the multinationals "have their exit strategies ready."

¶3. (U) According to news reports over the last three months, the Pakistan Pharmaceutical Manufacturer's Association (PPMA) - representing domestic manufacturers - has sounded the alarm about pricing. They have appealed for a 15 to 20 percent adjustment in prices to account for inflation. PPMA has also called for a withdrawal of a 10 percent customs duty and 15 percent sales tax on raw and packaging materials used in the industry, and exempting pharmaceutical manufacturing imports from the 35 percent letter of credit margin imposed by the State Bank of Pakistan. According to press reports, Kashif Shaikh, president of the PPMA, called the pricing situation the worst crisis ever to affect the industry and said that it could result in an "acute shortage of drugs in Pakistan."

¶4. (SBU) The GOP's primary concern over pharmaceutical pricing is affordability. They said the Pharma Bureau of Information and Statistics, part of the Overseas Investors Chamber of Commerce and Industry (OICCI), was proposing an increase of 75 percent of Consumer Price Index (CPI) inflation for essential medications, and 100 percent of CPI inflation for non-essential medications. For the long term, they proposed the creation of a transparent government pricing system including yearly automatic price adjustments to

account for inflation, and they were prepared to accept price adjustment caps for times of hyperinflation. In the short term, however, they said a price adjustment to account for inflation was essential if Pakistan is to have hope of sustaining its pharmaceutical industry. (Comment: PPMA and the Pharma Bureau are usually in direct opposition to each other on issues, but the pricing issue is a clear exception.)

15. (U) Recent news reports state that Pakistan's 2008 Health Policy will be announced in September and that it will contain a pharmaceutical pricing mechanism that will address domestic and multinational pharmaceutical manufacturers' concerns. A Drugs Regulatory Authority is also expected to be established during the fall.

#### Data Protection

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16. (SBU) Bengali and Shaikh both said that an amendment to the 1976 Drugs Act regarding protection of undisclosed test and research data against unfair commercial use was still important to the Pharma Bureau, but had taken a back seat to the pricing issue. Shaikh expressed his frustration with the data protection situation saying that it seemed as if the issue had been "put in a drawer" and set aside by the MOH. An Expert Committee of stakeholders, including the MOH, the Pharma Bureau and PPMA, was formed in 2006 to review the draft amendment. This committee has not met since November 2007, in spite of the Ministry of Law's direction to the MOH to hold a meeting in February 2008. The February meeting was initially delayed until May, and ultimately was never held.

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17. (SBU) An added challenge has been the high turnover of officials at the MOH. Almost all the people originally involved in drafting the data protection amendment have left or been replaced. Bengali said they were reluctant to seek meetings with the MOH for fear that interlocutors would be here today, gone tomorrow.

#### Bilateral Investment Treaty

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18. (SBU) Econoff spoke about the current effort to revive Bilateral Investment Treaty (BIT) negotiations and asked about the pharmaceutical industry's interest in a BIT. Shaikh and Bengali said they thought the BIT would be very beneficial and that they would be willing to approach GOP officials and advocate for a BIT. They suggested post seek out other Pakistani trade organizations asking their support as well.

#### Comment

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19. (SBU) If the pricing issue is not satisfactorily resolved by the announcement of the 2008 Health Policy, multinational pharmaceutical companies may leave the Pakistani market completely. Although PPMA may desire less competition from multinationals, it would ultimately be a Pyrrhic victory, as the domestic manufacturers will almost certainly be unable to sustain operations under current market conditions. The undisclosed data protection issue remains frustratingly immobile, in spite of assurances from MOH officials that the legislation is close to being completed. The legislation has been "very close to completion" for at least six months, but has in that time not moved at all. Post will continue to follow up on all these issues. End comment.

PATTERSON